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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,790	02/11/2004	Jacqueline C. Timans	DX01040K3B	3044

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EXAMINER
JIANG, DONG

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,790	TIMANS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 26-57* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *16,26-31,33,37,38,40, 51, 52 and 54-57* is/are rejected.

7)☒ Claim(s) *32 and 53* is/are objected to.

8)☒ Claim(s) *16 and 26-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 30 May 2007 is acknowledged and entered. Following the amendment, claims 34-36 and 39 are canceled, and the new claims 51-57 are added.

Currently, claims 16 and 26-57 are pending, and claims 16, 26-33, 37, 38, 40 and 51-57 are under consideration to the extent that they read on the elected sequence.

Applicants continue to argue about the previous restriction requirement regarding SEQ ID NO:2 and 6 even though it was indicated in the last Office Action that the requirement is deemed proper and is therefore made FINAL. Applicants argue that the two sequences are shown to be identical in all but the first 10 and 11 amino acid respectively, and are identical for 232 amino acids out of 242 and 243 amino acids respectively, and that searching the sequence of 232 identical amino acids would provide an overlapping set of the reference with no undue burden. This is not found persuasive because the present claims encompass small fragments of the polypeptide, for example, 17 or 20 amino acids; thus, an oligomer search of SEQ ID NO:2 would not necessarily reveal anticipating art for the claimed fragments of SEQ ID NO:6. Therefore, separate searches are required for the each of the two sequences, which constitute an undue burden.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 34-36 and 39 are moot as the applicant has canceled the claim.

Formal Matters:

Drawings

The drawings/figures are objected to for the following reasons: the labeling in Figures 1 and 2 is confusing: on the left side of Figures 1 and 2, it is labeled "2" and "8" (Figure 1), and "10" and "4" (Figure 2). However, it unclear to what they refer because they do not seem to represent SEQ ID NO of the sequences since the figure legend in the specification (page 4) indicates that Figure 1

shows the comparison between SEQ ID NO:2 and 6; and Figure 2 shows the comparison between SEQ ID NO:4 and 8.

Clarification or appropriate correction is required.

Claims

Claims 16, 26-32, 38 and 40 remain objected to for encompassing a non-elected subject matter, SEQ ID NO:4, 6 and 8. The applicant is required to amend the claims to read only upon the elected invention.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation "wherein the chemical modification is ..., or *PEGylation*", however, the specification provides no basis for "PEGylation". Applicants point out, on page 10 of the response filed on 30 May 2007, that PEGylation and techniques for PEGylation are described in Lundblad and Noyes (1988) *Chemical Reagents for Protein Modifications* as cited at page 16 of the application, which reference is incorporated by reference as stated at page 55 of the specification. This is not persuasive because the cited reference teaches various techniques for protein modifications, and MPEP requires that particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found (608.01(p), I. A.).

This is a new matter rejection.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 26-31, 33, 37, 38 and 40 remain rejected, and the new claims 51, 52 and 55-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated polypeptide of SEQ ID NO:2 capable of binding to the receptor of SEQ ID NO:12, does not reasonably provide enablement for claims to an isolated polypeptide *comprising* at least 17, 20, 25, 30, 35, 50, or 75 amino acids of SEQ ID NO:2 (claims 16, 26-31 and 40, for example), or % variants of SEQ ID NO:2 (claims 38 and 39, for example), binding to any or all cell surface receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the last Office Action mailed on 06 February 2007, at pages 4-6.

Applicants argument filed on 30 May 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 8-9 of the response, the applicant argues that claims 16, 38 and 40 have been amended to recite that the claimed polypeptides bind to WSX-1/TCCR, that it is easily within the skill of a skilled artisan to generate and identify the claimed fragments with recited functionality without undue experimentation, and that such identification of the fragments will not require undue experimentation. This argument is not persuasive because the recited functionality is *not associated* with the claimed fragment, rather, it is the functional property of the polypeptide comprising the fragment, and such a polypeptide may or may not be structurally related to the polypeptide of SEQ ID NO:2 with the exception of a small fragment (17 amino acids, for example), which is not necessarily associated with the functional property. As such, the claimed polypeptide reads on a functional equivalent, and the specification provides no guidance or working examples as to how to make such functional equivalents. Further, the specification does not teach the structural and functional relationship of the polypeptide of SEQ ID NO:2, for example, whether a small portion of the polypeptide such as 17 amino acids is likely to possess the desired functional property (given the fact that the full length of the polypeptide is 242 amino acids), and which 17 amino acids are associated with the desired functional property (claim 16,

for example), or have the specific antigenecity of SEQ ID NO:2 (claim 37, for example). Therefore, large quantity of experimentation would be necessary to determine functional fragments and variants, which would constitute undue experimentation for the skilled artisan to make the claimed invention in its full scope.

Claims 16, 26-31, 33, 37, 38 and 40 remain further rejected, and the new claims 51, 52 and 55-57 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Action mailed on 06 February 2007, at pages 6-7.

Applicants argument filed on 30 May 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 9-10 of the response, the applicant argues that claims 16, 38 and 40 are amended to specify binding to WSX-1/TCCR; that Example 14 of the Written Description Guidelines indicates that variants of a single disclosed species claimed with a functional limitation has sufficient written description where the procedures for making variants are known and where an assay is described for identifying the presence of a claimed function; and that assays for identifying binding to WSX-1/TCCR are provided in the specification. This argument is not persuasive because opposed to the situation in Example 14 of the Guidelines, the present claims recite lower percent sequence identity (90% (claim 38) vs. the suggested 95% in the Guidelines, for example). Further, the issue is not whether the assays are provided in the specification, rather, it is that the specification fails to provide adequate written description for the claimed polypeptide, the functional equivalents of SEQ ID NO:2, which meet the limitation of the claims. Thus, a skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making it. 16, 26-33, 37, 38, 40 and 51-57

Conclusion:

No claim is allowed.

Claims 32 and 53 would be allowable if amended to overcome the objections thereto.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
7/26/07